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PATENT

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Applicant	:	Jiangchun Xu et al.
Application No.	:	09/657,279
Filed	:	September 6, 2000
For	:	COMPOSITIONS AND METHODS FOR THE THERAPY AND DIAGNOSIS OF PROSTATE CANCER

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entered in part

Examiner	:	Jehanne E. Souaya
Art Unit	:	1634
Docket No.	:	210121.427C19
Date	:	August 30, 2002

Commissioner for Patents
Washington, DC 20231

REPLY UNDER 37 C.F.R. § 1.111

Commissioner for Patents:

In response to the Office Action dated April 22, 2002, please extend the period for reply by two months, making the new due date for responding to this matter September 22, 2002. Enclosed herewith are a petition for an extension of time and the requisite fee. Please amend the application as follows:

AMENDMENT

In the Claims:

Please cancel claims 1-17.

Please add new claims 18-26 as follows:

18. (New) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:108.

28 ~~19.~~ (New) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:108, or a fragment thereof comprising at least 10 consecutive amino acid residues of SEQ ID NO:108.

29 ~~20.~~ (New) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:108, or a fragment thereof comprising at least 20 consecutive amino acid residues of SEQ ID NO:108.

30 ~~21.~~ (New) An isolated polypeptide comprising an amino acid sequence having at least 75% identity to the entirety of SEQ ID NO:108.

31 ~~22.~~ (New) An isolated polypeptide comprising an amino acid sequence having at least 85% identity to the entirety of SEQ ID NO:108.

32 ~~23.~~ (New) An isolated polypeptide comprising an amino acid sequence having at least 95% identity to the entirety of SEQ ID NO:108.

33 ~~24.~~ (New) An isolated polypeptide having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO:108.

34 ~~25.~~ (New) An isolated polypeptide having at least 95% identity to an amino acid sequence comprising at least 10 consecutive amino acid residues of SEQ ID NO:108.

35 ~~26.~~ (New) A fusion protein comprising a polypeptide according to any one of claims 27-34 ~~18-25~~.

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Applicants note that a Preliminary Amendment was mailed by Applicants on April 18, 2002, but apparently did not reach the Examiner prior to issuance of the Office Action dated April 22, 2002. Accordingly, for purposes of this Response, it is assumed that the Preliminary Amendment was not and will not be entered. Accordingly, the amendments and remarks herein are based upon originally elected claims 2 and

7, and the polypeptide sequence of SEQ ID NO:108, elected in response to the Restriction Requirement dated February 19, 2002.

Claims 1-17 have been cancelled and new claims 18-26 have been added. It is urged that support for the above amendments can be found throughout the specification as originally filed and that none of the amendments constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections, and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Corrected drawings are submitted herewith in reply to the Examiner's request.

Rejection Under 35 U.S.C. § 112, First Paragraph (enablement)

Claims 2 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification allegedly does not enable any person skilled in the art to make or use the invention commensurate in scope with the current claims. The Examiner acknowledges that the specification is enabling for an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:108 and fusion proteins comprising SEQ ID NO:108. The Examiner further acknowledges that the polypeptide of SEQ ID NO:108 has a differential expression pattern in prostate cancer tissue relative to normal prostate tissue. Despite this disclosure, however, the Examiner takes the position that the specification does not reasonably provide enablement for any portions or variants of SEQ ID NO:108, apparently because the specification has allegedly not taught the activity or biological function common to the claimed genus of polypeptides. For example, the Examiner takes the position that :

> "Since the specification does not teach the specific biological function or activity of , and neither the specification nor the art teach how the function of the polypeptide is associated to prostate cancer nor how the skilled artisan could modify the polypeptide of SEQ ID NO:108 to obtain a polypeptide with either retained or modified function in association with it's differential expression in prostate cancer, the skilled artisan would be required to perform undue experimentation to make or use the biologically active or altered polypeptides encompassed by the broadly claimed invention."

Applicants respectfully traverse this basis of rejection and submit that the specification does, in fact, provide enablement for the claimed invention. As set forth in the above amendment, newly added claims 18-26 are drawn to isolated polypeptides comprising

SEQ ID NO:108, isolated polypeptides comprising at least 10 consecutive amino acid residues of SEQ ID NO:108, isolated polypeptides having at least 75% identity to the entirety of SEQ ID NO:108 and isolated polypeptides having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO:108. Thus, in order to practice the claimed invention, the skilled artisan simply needs to understand how to make and use fragments of SEQ ID NO:108 and how to make and use sequences having some defined degree of structural identity to SEQ ID NO:108. This subject matter is indeed fully enabled by Applicants' specification as originally filed, wherein extensive illustrative guidance regarding making and using fragments and variants of Applicants' cancer associated sequence is offered for example on page 37, line 16 through page 39, line 2, as well as page 43, line 4 through page 44, line 28 and elsewhere in the specification.

Applicants further submit that it is the prostate tumor-associated expression profile of SEQ ID NO:108, not its biological function, that is most pertinent to enablement of the presently claimed polypeptides. The skilled artisan, for example, would appreciate that the biological function of the claimed polypeptides is irrelevant to its over-expression in cancer tissue relative to normal tissue and, similarly, is irrelevant to the recognition on the part of the skilled artisan as to how fragments and variants of SEQ ID NO:108 can be made and used in the context of Applicants' disclosure.

As acknowledged by the Examiner, SEQ ID NO:108 possesses a prostate cancer-associated expression profile sufficient to distinguish prostate cancer tissue from normal prostate tissue. In view of this disclosure, the individual skilled in the diagnostic arts would most certainly appreciate that SEQ ID NO:108 can be used, for example, as a diagnostic marker for prostate cancer. In one illustrative scenario, for example, the species of SEQ ID NO:108 can be used to generate antibodies that, based upon their specificity for SEQ ID NO:108, can be used to detect prostate cancerous tissue using routine and art-recognized immunohistochemical (IHC) analysis.

Applicants submit that the skilled artisan would further appreciate, in view of this disclosure, that the genus encompassed by fragment and % identity language of the current claims are also fully enabled by the specification. More particularly, the skilled artisan, upon accepting that SEQ ID NO:108 can be used to make prostate cancer-specific diagnostic antibodies, would also understand that the claimed fragments and variants of SEQ ID NO:108

can be used in the very same context and to the same extent as the specific species of SEQ ID NO:108, despite the fact that they are not identical to the species of SEQ ID NO:108. For example, based upon fundamental principles of immunological recognition and antibody cross-reactivity, it would be understood that the claimed genus of fragments of SEQ ID NO:108 can be made and used, without undue experimentation, to generate antibodies that are specific for SEQ ID NO:108, and are thus useful in the context of Applicants' disclosure in the same manner as for SEQ ID NO:108. Moreover, it would be further understood that the claimed genus of variants of SEQ ID NO:108, e.g., sequences related by structural identity to SEQ ID NO:108, can similarly be made and used, without any undue experimentation, to generate antibodies that are specific for, i.e., cross-reactive with, the species of SEQ ID NO:108. As the individual skilled in the diagnostic arts would understand and concur that such fragments and variants of SEQ ID NO:108 can be readily and routinely made and used in the context of Applicants disclosure, they are submitted to fall squarely within the scope of enabled subject matter.

Accordingly, Applicants urge that a skilled individual, in light of the guidance set forth in the instant specification, and further in view of the level of general knowledge in this art, would know how to make and use Applicants' claimed genus of fragment and variant polypeptides without undue experimentation. Reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph (written description)

Claims 2 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicants, at the time the application was filed, had possession of the claimed invention. The Examiner acknowledges that Applicants are in possession of SEQ ID NO:108 and that this polypeptide has a prostate cancer-associated expression pattern. However the Examiner asserts that the specification has not described a biological function or activity of SEQ ID NO:108 and concludes on this basis that Applicants were not in possession of any sequence other than the species of SEQ ID NO:108.

Applicants respectfully traverse this rejection and submit that the specification more than adequately describes relevant and distinguishing identifying characteristics sufficient to establish that Applicants were in possession of the genus of polypeptides currently claimed.

Applicants further submit that biological function is but one example of an identifying characteristic sufficient to support a claimed genus of polypeptides. Under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, "Written Description" Requirement, 66 Fed. Reg. 1099, at 1106 (emphasis added).

Applicants submit that an illustrative sufficient and relevant identifying characteristic shared by members of the currently claimed genus is their ability to be used in the detection of prostate cancer. As noted above, the biological function of the polypeptide of SEQ ID NO:108 is not relevant to its over-expression in cancer tissue relative to normal tissue or to its ability to be used in the detection of prostate cancer, and would be recognized as such by the skilled individual. Accordingly, Applicants submit that the prostate tumor-associated expression profile of P504S represents an identifying characteristic, described in the specification as filed, sufficient to convey to the artisan skilled in the diagnostic arts that applicants were in possession of the claimed genus of polypeptides.

Given Applicants' disclosure of the novel P504S polypeptide of SEQ ID NO:108, in conjunction with Applicants' discovery that this polypeptide is over-expressed in prostate cancer tissue relative to normal tissues, the skilled artisan would immediately recognize Applicants were in possession of much more than the specific sequence of SEQ ID NO:108. In view of this disclosure, and further in view of the level of general knowledge in this art, the skilled artisan would understand and expect that a genus of polypeptides structurally related to SEQ ID NO:108, e.g., sequences having at least 75%, 85% or 95% identity to SEQ ID NO:108, would also be useful in the context of Applicants' invention, in the same manner as for the specific sequence of SEQ ID NO:108. For example, the skilled artisan would appreciate that such sequences related to SEQ ID NO:108 can be used, for example, in generating diagnostic reagents, e.g., antibodies having specificity for a polypeptide sequence of SEQ ID NO:108, and useful in the detection of prostate cancer tissue, despite the fact that the sequences are not identical with the specific sequence of SEQ ID NO:108. This understanding and expectation on the part of the skilled artisan is submitted to be soundly based upon fundamental scientific

principles, namely that polypeptides related to, but not identical with, SEQ ID NO:108, can nonetheless be used to generate antibodies that are cross-reactive with Applicants' species of SEQ ID NO:108, and are thus useful in the detection of prostate cancer according to Applicants' disclosure. Thus, to accept the Examiner's position that Applicants were only in possession of the specific species of SEQ ID NO:108 would improperly exclude an entire class of polypeptides structurally related to SEQ ID NO:108 that the skilled individual would understand were in Applicants' possession at the time of filing.

Reconsideration of the Examiner's rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, the Examiner views as indefinite Applicants' use of the phrases "recited in" and "provided in."

As set forth above, claims 2 and 7 have been cancelled, without prejudice or acquiescence, and new claims 18-26 have been added. New claims 18-26 are drawn to isolated polypeptides comprising SEQ ID NO:108, isolated polypeptides comprising at least 10 consecutive amino acid residues of SEQ ID NO:108, isolated polypeptides having at least 75% identity to the entirety of SEQ ID NO:108, *etc*. Applicants respectfully submit that the phrases "recited in" and "provided in" are not present in new claims 18-26 and, accordingly, respectfully request reconsideration and withdrawal of the Examiner's rejection.

Rejections Under 35 U.S.C. § 102

Claim 2 stands rejected under 35 U.S.C. § 102(a) as being anticipated by Accession number AAB72146. According to the Examiner, AAB72146 teaches a polypeptide having 73% identity to the full length polypeptide of SEQ ID NO:108 and also teaches that amino acid residues 1-8 of AAB72146 are identical to amino acid residues 22-29 of SEQ ID NO:108. On this basis, the Examiner asserts that claim 2 is anticipated due to Applicants' use of the phrase "recited in" in section (a), and because sections (b) and (c) do not specify that the % identity is over the "full length" of the polypeptide.

The Examiner also rejects claim 2 under 35 U.S.C. § 102(b) over Haldenwang, on the basis that this reference teaches that amino acid residues 19-25 are identical to amino acid residues 248-254 of SEQ ID NO: 8, and thus anticipates claim 2 due to Applicants' use of the phrase "recited in" in section (a), and because sections (b) and (c) do not specify that the % identity is over the "full length" of the polypeptide.

The Examiner also rejects claim 2 under 35 U.S.C. § 102(b) over JP06038763, on the basis that this reference teaches that amino acid residues 126-134 of a 394 amino acid polypeptide disclosed by this reference are encoded by nucleotides 362-388 of SEQ ID NO: 107, and thus anticipates claim 2, section (d).

Applicants respectfully traverse these rejections. As set forth in the above amendment, new claims 18-26 are drawn to isolated polypeptides comprising SEQ ID NO:108, isolated polypeptides comprising at least 10 consecutive amino acid residues of SEQ ID NO:108, isolated polypeptides having at least 75% identity to the entirety of SEQ ID NO:108 and isolated polypeptides having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO:108. This currently claimed subject matter is submitted to be clearly novel over the references cited by the Examiner as the sequences corresponding to these accession numbers simply do not teach, as currently claimed, any isolated polypeptides comprising SEQ ID NO:108, any isolated polypeptides comprising at least 10 consecutive amino acid residues of SEQ ID NO:108, any isolated polypeptides having at least 75% identity to the entirety of SEQ ID NO:108, or any isolated polypeptide having at least 90% identity to an amino acid sequence comprising at least 20 consecutive amino acid residues of SEQ ID NO:108. As the cited sequences fail to teach each and every element of the presently claimed invention, Applicants respectfully request reconsideration and withdrawal of these rejections under 35 U.S.C. § 102.

Provisional Double Patenting Rejection

Claim 2 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of copending Application Nos. 09/568,100, 09/636,215, 09/593,793 and 09/605,783. The Examiner notes that this is a provisional obviousness-type double patenting rejection because the potentially conflicting claims have not been patented. Applicants acknowledge this provisional rejection and

respectfully submit that this issue will be addressed in due course, upon identification of allowable subject matter in the instant application.

Favorable reconsideration and allowance of the currently pending claims are respectfully solicited. The Examiner is invited to contact the undersigned at 206-694-4885 with any questions, comments and/or suggestions pertaining to this communication.

Respectfully submitted,

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